

DETAILED ACTION

The amendment filed 01/19/10 affects the application, 10/573,973 as follows:

1. Claims 1, 3, 5, 6 have been amended. The rejections made under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 102 and 103(a) of the prior office action mailed 10/16/09 are maintained. Also, a new ground(s) rejection is set forth herein below. In addition, it should be noted the rejections made under 35 U.S.C. 102 and 103(a) by applying the Shionogi and Co., Ltd. reference in the office action mailed 02/05/09 have been reinstated due to applicant's amendments.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-3, 5-10 are pending in application

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 8 should be renumbered as claim 11 since claim 8 has been previously canceled. That is, Claim 8 which was previously canceled is now added (or re-instated) and is presently numbered as Claim 8. However, when claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). Appropriate correction is required.

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It should be noted that applicant has presently amended claims 1-3, 5 and 6 and have not indicated the amendments made to said claims via marked up. That is, applicant has not underlined or striking through the added or deleted segments, phrases or portion of the claims that have been amended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the phrase “a protective group selected from a hydroxyl group, a phosphate group, or a protected phosphate group”. However, the claim is indefinite since it is unclear how a hydroxyl group can be a protected group. Also, it is unclear what the difference between a protective group selected from a phosphate group and a protected phosphate group. That is unclear what constitutes a protective group selected from a phosphate group as compared to a protected phosphate group as recited in the claim.

Claim 6 recites the phrase “stabilizing a calcium pantothenate”. However, the claim is indefinite since it is unclear how said calcium pantothenate is stabilized or what it is stabilized from or what constitutes a stabilization.

Claim 7 recites the phrase “wherein the stability of the vitamin is improved”. However, the claim is indefinite since it is unclear how said vitamin is stabilized or what it is stabilized from or what constitutes a stabilization or an improved stability.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for improving the stability of specific vitamin such as calcium pantothenate (vitamin B5, VB5) from thermal decomposition and decomposition initiated by U.V. light in a cosmetic, a medicament, a foodstuff, and/or a feed by adding said compound to said cosmetic, a medicament, a foodstuff, and/or a feed, it does not reasonably provide enablement for stabilizing (in general or broadly) calcium pantothenate in said composition by adding the compound of general formula (V) or a salt thereof to a cosmetic, a medicament, a foodstuff, and/or a feed .

For example, the stabilization of calcium pantothenate which broadly includes (as example) the inhibition of reactions between two or more other chemicals such as a reaction of calcium pantothenate with a one or more chemicals or components of the said composition and which also broadly includes (as example) the inhibition of the separation of calcium pantothenate from applicant claimed cosmetics, medicament, foodstuff or feed compositions which can be in the form of suspensions, emulsions, and foams (as example) and can comprise all or any one of the numerous chemicals, ingredients or substances of completely different chemical structures, functional chemical groups and properties (in general) that can be used in cosmetics, medicament, foodstuff or feed compositions, would reasonably broadly encompass the stabilization of said calcium pantothenate with all those known and unknown

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chemicals, ingredients or substances as of the instant filing date, as well as those future known chemicals, ingredients or substances yet to be discovered or prepared which have completely different chemical structures, functional chemical groups and properties.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. The nature of the invention: The instant invention pertains to a method for stabilizing calcium pantothenate contained in a cosmetic, a medicament, a foodstuff, and/or a feed by adding a compound represented by the general formula (V) or a salt thereof mentioned in claim 5 to the cosmetic, the medicament, the foodstuff, and/or the feed.

2. The state of the prior art: The skilled artisan would view the stabilization of calcium pantothenate (from all the numerous causes of destabilization including the stabilization of calcium pantothenate from a reaction of calcium pantothenate with one or more chemicals or components) in a composition wherein the chemicals or components of the composition includes all the numerous substances which have different chemical structures and properties by adding a specific compound to a cosmetic, a medicament, a foodstuff, and/or a feed, as not possible.

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3. The predictability of the art, and the breadth of the claims:

It is highly unpredictable what type of reaction or property or cause of the calcium pantothenate can be stabilized by said compound and what particular ingredients or components must comprise the said cosmetic, a medicament, a foodstuff, and/or a feed in order for said stabilization to occur as required by the claim. Such determination would require numerous or several trials and experimental processes. Also, the amounts or quantity of the compound to be added and the amount or quantity and types of ingredients or components that comprises the said cosmetic, a medicament, a foodstuff, and/or a feed is unpredictable. That is, there is no routine, predictable way to prepare and stabilize calcium pantothenate by addition of a specific compound to a composition comprising all the numerous chemicals, components or substances in each and every composition of calcium pantothenate /compound in a cosmetic, a medicament, a foodstuff, and/or a feed form. Thus, the said preparation would require unpredictable experimentation. Furthermore, it should be noted that the claim requires that the said compound be able to stabilize calcium pantothenate regardless of the causes of the lack of stability and all the numerous components or chemicals with their different structures, functions and functional groups and properties as a whole and consequently this is highly unpredictable.

4. The presence or absence of working examples: It is noted that the specification merely provides a working example to demonstrate improving the stability of the vitamin calcium pantothenate (vitamin B5, VB5) by dissolving or adding a vitamin B6 derivative and calcium pantothenate (vitamin B5, VB5) in purified water and observing substantially no decomposition (see page 38). That is, the evidence in the examples provided is not commensurate in scope with

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the claimed invention and does not demonstrate criticality of the numerous compounds that are encompassed by applicant's claimed method. See MPEP § 716.02(d).

Furthermore, it should be noted that the applicant states that "the inventors of the present invention also found that the aforementioned vitamin B6 derivative was stably maintained in a composition such as medicaments, foodstuffs, feeds, cosmetics and the like to exhibit superior effects, **and the derivative gave no influence on the stability of other vitamins in the composition**" (see page 3, 1st paragraph). Therefore, the skilled artisan has to exercise undue experimentation to practice the instant invention.

Thus, the specification fails to provide sufficient support of the method of broadly stabilizing calcium pantothenate in a composition by adding the said compound regardless of the causes of the lack of stability and presence of all the numerous components or chemicals with their different structures, functions and functional groups and properties in the composition as encompassed by the instant claim. As a result, necessitating one of skill to perform an exhaustive search for the embodiments and method of preparations of said composition that are encompassed by the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factor and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in

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undue experimentation to test compounds and compositions encompassed in the instant claims, with no assurance of success.

Claim Rejections - 35 USC § 102

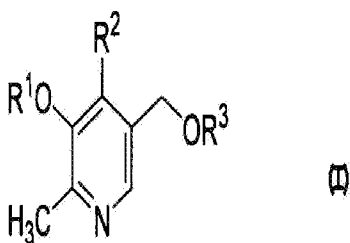
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mineura et al. (Nippon Noge Kagaku Kaishi (1972), 46(3), 111-18, Abstract Only).

Claim 1 is drawn to a compound represented by the following general formula (I) or a salt thereof:



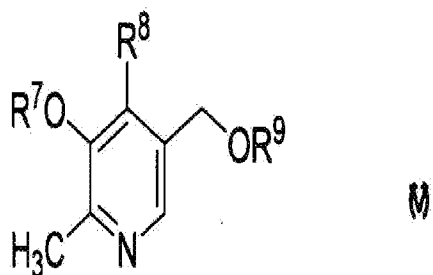
wherein R¹ represents a phosphate or a cyclic phosphate group bound to R²; R² represents -CH₂OH, -CHO, -CH₂NH₂, -CH₂-amino acid residue, or -CH₂-OPO₂H; and R³ represents hydrogen atom, or -PO₃H₂. Mineura et al. disclose applicant's compound represented by the general formula (I) wherein R¹ represents a cyclic phosphate group bound to R²; R² represents -CH₂OH; and R³ represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1,

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3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract).

Claim 2 is drawn to the compound or a salt thereof according to claim 1, which is selected from the group consisting of pyridoxine 3-phosphate, pyridoxine 3,4'cyclic phosphate, and N-(4 pyridoxylmethylene)-L-serine 3-phosphate, or a salt thereof. Mineura et al. disclose applicant's compound, pyridoxine 3,4'cyclic phosphate (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract).

In claim 5, applicant claims a composition for a cosmetic, a medicament, a foodstuff, and/or a feed comprising a compound represented by the following general formula (V) or a salt thereof:



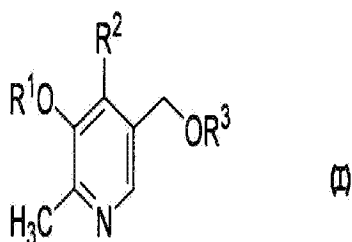
wherein R⁷ represents a phosphate group, a sulfate, or a cyclic phosphate group bound to R⁸; R⁸ represents -CH₂OH, -CHO, -CH₂NH₂, -CH₂-amino acid residue, or -CH₂-OPO₂H; and R₉ represents hydrogen atom, or -PO₃H₂. Mineura et al. disclose applicant's composition or compound represented by the general formula (V) wherein R⁷ represents a cyclic phosphate group bound to R⁸; R⁸ represents -CH₂OH; and R⁹ represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that

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applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for a cosmetic or a medicament, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claims 1-3, 5, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shionogi and Co., Ltd. (FR 2196793 A2, Abstract Only).

In claim 1, applicant claims a compound represented by the following general formula (I) or a salt thereof:

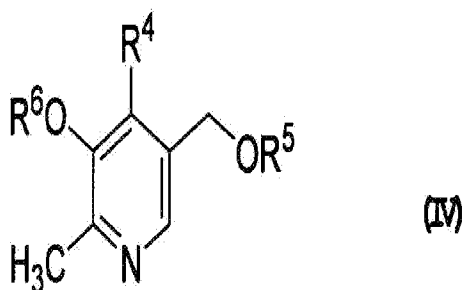


wherein R¹ represents a phosphate group or a cyclic phosphate group bound to R²; R² represents -CH₂OH, -CHO, -CH₂NH₂, -CH₂-amino acid residue, or -CH₂-OPO₂H; and R³ represents hydrogen atom, or -PO₃H₂. Shionogi and Co., Ltd. disclose applicant's compound represented by the general formula (I) wherein R¹ represents a phosphate group; R² represents -CH₂OH; and R³ represents hydrogen atom (see abstract). Shionogi and Co., Ltd.'s compound has a Cas # of 1883-15-4 (see abstract). It should be noted that applicant's compound is also named 5'-pyridoxine phosphate and 3,4-pyridinedimethanol,6-methyl-5-(phosphonooxy)- (see abstract).

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Claim 2 is drawn to the compound or a salt thereof according to claim 1, which is selected from the group consisting of pyridoxine 3-phosphate, pyridoxine 3,4'cyclic phosphate, and N-(4 pyridoxylmethylene)-L-serine 3-phosphate, or a salt thereof. Shionogi and Co., Ltd.'s disclose applicant's compound, pyridoxine 3-phosphate (see abstract). Shionogi and Co., Ltd.'s compound has a Cas # of 1883-15-4 (see abstract). It should be noted that applicant's compound is also named 5'-pyridoxine phosphate and 3,4-pyridinedimethanol,6-methyl-5-(phosphonooxy)- (see abstract).

Claim 3 is drawn to a compound represented by the following general formula (IV) or a salt thereof:

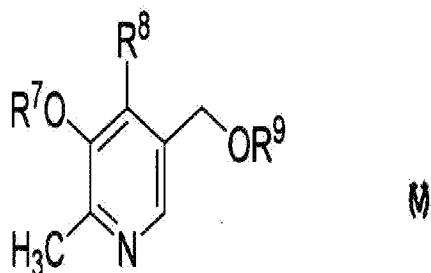


wherein R⁴ represents -CH₂OH, -CHO, or -CH₂NH₂, or represents -CH₂OH, -CHO, or -CH₂NH₂ protected with a protective group; R⁵ represents hydrogen atom, a protective group of hydroxyl group, a phosphate group, or a protected phosphate group; and R⁶ represents a phosphate group which may have a protective group. Shionogi and Co., Ltd. disclose applicant's compound represented by the general formula (IV) wherein R⁶ represents a phosphate group; R⁴ represents -CH₂OH; and R⁵ represents hydrogen atom (see abstract). Shionogi and Co., Ltd.'s compound has a Cas # of 1883-15-4 (see abstract). It should be noted that applicant's compound

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is also named 5'-pyridoxine phosphate and 3,4-pyridinedimethanol,6-methyl-5-(phosphonooxy)- (see abstract).

In claim 5, applicant claims a composition for a cosmetic, a medicament, a foodstuff, and/or a feed comprising a compound represented by the following general formula (V) or a salt thereof:



wherein R⁷ represents a phosphate group, a sulfate group, or a cyclic phosphate group bound to R⁸; R⁸ represents -CH₂OH, -CHO, -CH₂NH₂, -CH₂-amino acid residue, or -CH₂-OPO₂H; and R⁹ represents hydrogen atom, or -PO₃H₂. Shionogi and Co., Ltd. disclose applicant's composition or compound represented by the general formula (V) wherein R⁷ represents a phosphate group; R⁸ represents -CH₂OH; and R⁹ represents hydrogen atom (see abstract). Shionogi and Co., Ltd.'s compound has a Cas # of 1883-15-4 (see abstract). It should be noted that applicant's compound is also named 5'-pyridoxine phosphate and 3,4-pyridinedimethanol,6-methyl-5-(phosphonooxy)- (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for a cosmetic or a medicament, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

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In claim 8, applicant claims the composition for cosmetics according to claim 5, which is a whitening agent, an anti-aging agent, and/or an agent for suppressing wrinkle formation by exposure to ultraviolet light. Shionogi and Co., Ltd. disclose applicant's composition or compound represented by the general formula (V) wherein R⁷ represents a phosphate group; R⁸ represents -CH₂OH; and R⁹ represents hydrogen atom (see abstract). Shionogi and Co., Ltd.'s compound has a Cas # of 1883-15-4 (see abstract). It should be noted that applicant's compound is also named 5'-pyridoxine phosphate and 3,4-pyridinedimethanol,6-methyl-5-(phosphonooxy)- (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for a cosmetic or a medicament, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. It should be noted that Trumbo et al.'s compound or composition is the same as applicant's and therefore it should inherently possess the same property of being a whitening agent or an anti-aging agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mineura et al. (Nippon Nogei Kagaku Kaishi (1972), 46(3), 111-18, Abstract Only).

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In claim 7, applicant claims a composition for a cosmetic, a medicament, foodstuff, and/or a feed containing a compound represented by the general formula (V) or a salt thereof mentioned in claim 5 and at least one kind of vitamin, wherein stability of the vitamin is improved.

Mineura et al. disclose applicant's composition or compound represented by the general formula (V) wherein R^7 represents a cyclic phosphate group bound to R^8 ; R^8 represents $-CH_2OH$; and R^9 represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). Also, it is known in the art that Mineura et al.'s compound can be utilized as vitamin B6 (pyridoxine).

The difference between applicants claimed composition and the composition of Mineura et al. is that applicant's composition also contains another vitamin.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of Mineura et al.'s compound and another vitamin which have the same utility in order to use it in nutritive, food stuff or a medicament.

One having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of Mineura et al.'s compound and another vitamin which have the same utility in order to use it in a nutritive, a food stuff or a medicament. It should be noted that it is obvious to determine the properties of the prepared composition or the components of the composition such as the stability of the components of the composition.

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Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savini Emile Constantin (FR 2349330 A) in view of Mineura et al.(Nippon Nogeï Kagaku Kaishi (1972), 46(3), 111-18, Abstract Only).

Claim 9 is drawn to a composition comprising (A) a compound represented by the general formula (V) according to claim 5, and (B) one or more kinds of substances selected from the group consisting of a whitening agent, an antioxidant, an antiphlogistic, a circulation accelerator, a cell activation agent, and an ultraviolet absorber, which is used as a whitening agent, an anti-aging agent, and/or an agent for suppressing wrinkle formation by exposure to ultraviolet light. Claim 10 is drawn to a whitening agent containing (A) a compound represented by the general formula (V) mentioned in claim 5, and (B) arbutin.

Savini Emile Constantin discloses that compositions comprising a pyridoxine and an antioxidant which can be used to treat hyperlipidaemia (see abstract).

The difference between applicants claimed composition and the composition of Savini Emile Constantin is the specific pyridoxine compound used.

Mineura et al. disclose a compound represented by the general formula (V) wherein R⁷ represents a cyclic phosphate group bound to R⁸; R⁸ represents -CH₂OH; and R⁹ represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). Also, it is known in the art that Mineura et al.'s compound can be utilized as vitamin B6 (pyridoxine).

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of a pyridoxine such as Mineura et al.'s pyridoxine compound and an antioxidant to treat hyperlipidaemia, since Savini Emile Constantin discloses that a pyridoxine and an antioxidant can be used.

One having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of a pyridoxine such as Mineura et al.'s pyridoxine compound and an antioxidant to treat hyperlipidaemia, since Savini Emile Constantin discloses that a pyridoxine and an antioxidant can be used. It should be noted that claim 10 is also encompassed by this rejection since it is obvious to use an antioxidant such as arbutin, since Savini Emile Constantin disclose that a pyridoxine and an antioxidant can be used. Also, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for a whitening agent, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shionogi and Co., Ltd. (FR 2196793 A2, Abstract Only).

In claim 7, applicant claims a composition for a cosmetic, a medicament, foodstuff, and/or a feed containing a compound represented by the general formula (V) or a salt thereof mentioned in claim 5 and at least one kind of vitamin, wherein stability of the vitamin is improved.

Shionogi and Co., Ltd. disclose applicant's compound represented by the general formula (I) wherein R¹ represents a phosphate group; R² represents -CH₂OH; and R³ represents hydrogen atom (see abstract). Shionogi and Co., Ltd.'s compound has a Cas # of 1883-15-4 (see abstract).

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It should be noted that applicant's compound is also named 5'-pyridoxine phosphate and 3,4-pyridinedimethanol,6-methyl-5-(phosphonooxy)- (see abstract). Also, it is known in the art that Shionogi and Co., Ltd.'s compound can be utilized as vitamin B6 (pyridoxine).

The difference between applicants claimed composition and the composition of Shionogi and Co., Ltd. is that applicant's composition also contains another vitamin.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of Shionogi and Co., Ltd.'s compound and another vitamin which have the same utility in order to use it in nutritive, food stuff or a medicament.

One having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of Shionogi and Co., Ltd.'s compound and another vitamin which have the same utility in order to use it in a nutritive, a food stuff or a medicament.

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 5-10 have been considered but are not found convincing.

The applicant argues that claim 7 is clear and definite and that one of ordinary skill in the art would immediately know what is meant by the phrase "wherein the stability of the vitamin is improved." Applicants further submit that the phrase "wherein the stability of the vitamin is improved" is also clear and definite in view of the specification. In particular, the specification describes how compounds of the claimed subject matter improve the stability of a vitamin, for example, in Example 16 on page 38. However, Claim 7 recites the phrase "wherein the stability

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of the vitamin is improved". But, the claim is indefinite since it is unclear how said vitamin is stabilized or what it is stabilized from or what constitutes a stabilization or an improved stability.

The Applicant argues that Mineura discloses the study of conditions for the production of pyridoxal phosphate from pyridoxine 4',5'-cyclic phosphate (emphasis added), not pyridoxine 3,4'-cyclic phosphate or any "compound represented by the following general formula (I) or a salt thereof: wherein R^1 represents a phosphate group or a cyclic phosphate group bound to R^2 ; R^2 represents $-CH_2OH$, $-CHO$, $-CH_2NH_2$, $-CH_2$ -amino acid residue, or $-CH_2-OPO_2H$; and R^3 represents a hydrogen atom, or $-PO_3H_2$." However, Mineura's compound is the same as applicant's claimed compound. That is, Mineura et al. disclose applicant's compound represented by the general formula (I) wherein R^1 represents a cyclic phosphate group bound to R^2 ; R^2 represents $-CH_2OH$; and R^3 represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). Furthermore, it should be noted that structure of applicant's claimed compound of formula (I) is the same or identical as the structure of the Mineura et al.'s compound, regardless of what applicant claims is being studied by Mineura's (see abstract). That is, Mineura et al. disclose the same compound claimed by applicant.

The Applicant argues that the Abstract of the Mineura document cited in the rejection includes the chemical structure for RN 36944-85-1, a pyridoxine 3,4'-cyclic phosphate. The association of this chemical structure with Mineura's disclosure of "pyridoxine 4',5'-cyclic phosphate" is therefore in obvious error. One of ordinary skill in the art would immediately know that the chemical structure for RN 36944-85-1 is not "pyridoxine 4',5'-cyclic phosphate."

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Accordingly, Mineura does not disclose a compound which is encompassed by Applicants' claimed subject matter. However, the compound disclosed by Mineura et al. has the chemical structure for RN 36944-85-1, a pyridoxine 3,4'-cyclic phosphate which is the same compound of formula (I) claimed by Applicant and is not an error (see abstract). Also, it should be noted that this compound has a Cas # (RN 36944-85-1) and was disclosed and well known or published before applicant instant invention. That is, the Cas# (RN 36944-85-1) identifies the same compound as that claimed by Applicant.

The Applicant argues that Applicants submit herewith a copy of Mineura et al. (Nippon Nogeï Kagaku Kaishi 46(3):103-110, 1972), i.e., Part I. of Mineura's "Studies on the Production of Pyridoxal Phosphate." This article is also from the same issue of the same journal cited in the instant rejection. Applicants submit that the chemical structure of the "pyridoxine 4',5'-cyclic phosphate" disclosed in the Abstract is actually the structure set forth in Figure 1 on page 104 of Part I of Mineura's studies, and not the structure associated with RN 36944-85-1 as set forth incorrectly in the Abstract cited by the Office. However, the reference cited by Applicant is not the same as the reference cited by the Examiner. The reference cited by the Examiner is Mineura et al. (Nippon Nogeï Kagaku Kaishi (1972), 46(3), 111-18) whereas the reference cited by Applicant is (Mineura et al. (Nippon Nogeï Kagaku Kaishi 46(3):103-110, 1972), i.e., Part I. of Mineura's "Studies on the Production of Pyridoxal Phosphate" (see references cited).

The Applicant argues that in further support thereof, Applicants submit the chemical structure of RN 14141-47-0, which structure is associated with Part I of Mineura's studies, i.e., Mineura et al. (Nippon Nogeï Kagaku Kaishi 46(3): 103-110, 1972). This structure is the same as

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that set forth in Figure 1 on page 104, and the same as the "pyridoxine 4',5'-cyclic phosphate" disclosed in the Mineura Abstract cited in the rejection. As can be clearly seen, the chemical structure for "pyridoxine 4',5'-cyclic phosphate" is not the same as Applicant's claimed pyridoxine 3,4'-cyclic phosphate and is not encompassed by any of Applicants' claimed compound[s] represented by the following general formula (I) or a salt thereof. However, the reference cited by Applicant is not the same as the reference cited by the Examiner. The reference cited by the Examiner is Mineura et al. (Nippon Nogeï Kagaku Kaishi (1972), 46(3), 111-18) whereas the reference cited by Applicant is (Mineura et al. (Nippon Nogeï Kagaku Kaishi 46(3):103-110, 1972), i.e., Part I. of Mineura's "Studies on the Production of Pyridoxal Phosphate" (see references cited). Moreover, the compound disclosed by Mineura et al. has the chemical structure for RN 36944-85-1, a pyridoxine 3,4'-cyclic phosphate which the same compound of formula (I) claimed by Applicant and is not an error (see abstract). The compound disclose by Mineura et al. does not have RN 14141-47-0. Also, it should be noted that Mineura et al.'s compound has a Cas # (RN 36944-85-1) and was disclosed and well known or published before applicant instant invention. That is, the Cas# (RN 36944-85-1) identifies the same compound as that claimed by Applicant.

The Applicant argues that as in *In re Yale*, Applicants respectfully submit that one of ordinary skill in the art upon reviewing the Mineura Abstract cited by the Office would mentally disregard or mentally substitute the erroneous chemical structure associated with the disclosure of "pyridoxine 4',5'- cyclic phosphate." However, the reference cited by Applicant is not the same as the reference cited by the Examiner. The reference cited by the Examiner is Mineura et al. (Nippon Nogeï Kagaku Kaishi (1972), 46(3), 111-18) whereas the reference cited by

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Applicant is (Mineura et al. (Nippon Nogeï Kagaku Kaishi 46(3):103-110, 1972), i.e., Part I. of Mineura's "Studies on the Production of Pyridoxal Phosphate" (see references cited). Moreover, the compound disclosed by Mineura et al. has the chemical structure for RN 36944-85-1, a pyridoxine 3,4'-cyclic phosphate which the same compound of formula (I) claimed by Applicant and is not an erroneous chemical structure associated with the disclosure (see abstract). The compound disclose by Mineura et al. does not have RN 14141-47-0. Also, it should be noted that Mineura et al.'s compound has a Cas # (RN 36944-85-1) and was disclosed and well known or published before applicant instant invention. That is, the Cas# (RN 36944-85-1) identifies the same compound as that claimed by Applicant.

The Applicant argues that in response, Applicants submit that claim 7 is not unpatentable over Mineura for at least the reasons set forth above in response to the rejection under 35 U.S.C. § 102. In particular, Applicants submit that Mineura fails to disclose a compound encompassed by the claimed subject matter. Accordingly, Applicants submit that Mineura fails to meet each and every limitation of the claimed subject matter. However, Mineura's compound is the same as applicant's claimed compound. That is, Mineura et al. disclose applicant's compound represented by the general formula (I) wherein R^1 represents a cyclic phosphate group bound to R^2 ; R^2 represents $-CH_2OH$; and R^3 represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). Furthermore, it should be noted that structure of applicant's claimed compound of formula (I) is the same or identical as the structure of the Mineura et al.'s

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compound, regardless of what applicant claims is being studied by Mineura's (see abstract). That is, Mineura et al. disclose the same compound claimed by applicant.

The Applicant argues that, even if Mineura were to disclose a compound encompassed by Applicants' claimed subject matter, Mineura fails to disclose or suggest the advantageous effects of the claimed compounds and/or compositions, including the stability of the claimed subject matter and the ability of the claimed subject matter to stabilize compositions comprising Applicants' claimed compounds and one or more kinds of vitamins. In view of the unexpected, advantageous effects of Applicants' claimed compounds, and the lack of any disclosure of such advantageous effects with respect to the compounds disclosed in Mineura (which compounds are not even the same as those encompassed by Applicants' claimed subject matter), it would not have been obvious to one of ordinary skill in the art to prepare a composition comprising a combination of Mineura's compound and another vitamin. However as set forth in the above rejection, one having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of Mineura et al.'s compound and another vitamin which have the same utility in order to use it in a nutritive, a food stuff or a medicament. It should be noted that it is obvious to determine the properties of the prepared composition or the components of the composition such as the stability of the components of the composition.

The Applicant argues that Applicants further submit that Mineura, which discloses a compound different from that encompassed by the claimed subject matter, fails to cure the deficiencies of FR 2349330. Applicants further submit that the cited art, either alone or in combination, fails to disclose an agent comprising arbutin. Thus, the cited documents in combination fail to meet each and every limitation of the claims, especially with respect to claim

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10. However, Mineura's compound is the same as applicant's claimed compound. That is, Mineura et al. disclose applicant's compound represented by the general formula (I) wherein R^1 represents a cyclic phosphate group bound to R^2 ; R^2 represents $-CH_2OH$; and R^3 represents hydrogen atom (see abstract). Mineura et al.'s compound has a Cas # of 36944-85-1 (see abstract). It should be noted that applicant's compound is also named 4H-1, 3, 2-Dioxaphosphorino[4,5-c]pyridine-5-methanol, 2-hydroxy-8-methyl-, 2-oxide (see abstract). Furthermore, it should be noted that structure of applicant's claimed compound of formula (I) is the same or identical as the structure of the Mineura et al.'s compound, regardless of what applicant claims is being studied by Mineura's (see abstract). That is, Mineura et al. disclose the same compound claimed by applicant. Also, as set forth in the above rejection, one having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of a pyridoxine such as Mineura et al.'s pyridoxine compound and an antioxidant to treat hyperlipidaemia, since Savini Emile Constantin discloses that a pyridoxine and an antioxidant can be used. It should be noted that claim 10 is also encompassed by this rejection since it is obvious to use an antioxidant such as arbutin, since Savini Emile Constantin disclose that a pyridoxine and an antioxidant can be used. Also, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for a whitening agent, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

The Applicant argues that Applicants further submit that one of ordinary skill in the art would not have been motivated to combine FR 2349330, which is directed to the treatment of lipidemia, with Mineura, which is silent with respect to any potential therapeutic properties of

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the disclosed compound and with respect to the advantageous effects of the claimed subject matter, e.g., whitening. However, one having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of a pyridoxine such as Mineura et al.'s pyridoxine compound and an antioxidant to treat hyperlipidaemia, since Savini Emile Constantin discloses that a pyridoxine and an antioxidant can be used. It should be noted that it is obvious to use an antioxidant such as arbutin, since Savini Emile Constantin disclose that a pyridoxine and an antioxidant can be used. Also, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for a whitening agent, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Michael C. Henry
April 22, 2010.

/Traviss C McIntosh III/
Primary Examiner, Art Unit 1623
April 23, 2010